



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,496	08/01/2001	John P. Hall	P-5211	7112

26253 7590 06/17/2004

DAVID W. HIGHET, VP AND CHIEF IP COUNSEL
BECTON, DICKINSON AND COMPANY
1 BECTON DRIVE, MC 110
FRANKLIN LAKES, NJ 07417-1880

EXAMINER

QUAN, ELIZABETH S

ART UNIT	PAPER NUMBER
----------	--------------

1743

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/920,496

Applicant(s)

HALL ET AL.

Examiner

Elizabeth Quan

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☒ Claim(s) 20,21 and 23-25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 09082003
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Objections

1. Claims 20, 21, 23-25 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent claim 22 upon which dependent claim 23 depends already recites a curvilinear upper section. The other claims are also directed to the curvilinear configuration of the upper section that allows the phenomena in the claims to occur with subjecting the upper section to external forces.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 10-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Regarding claims 10, 22, the recitation "...the sidewalls being formed of resiliently flexible material of the lid so that when the lid is positioned above the surface of the multi-well plate and downward force is applied to the lid to press the over against the multi-well plate, the curvilinear concave shaped upper section resiliently deforms to cause the sidewalls to resiliently flex about the multi-well plate and, with continued application of downward force, the sidewalls resiliently grasp the multi-well plate to thereby straighten said upper section to a final, flexed position where the lid is secured to the multi-well plate with the upper section in closely

Art Unit: 1743

overlying relation to the multi-well plate surface...” raises the question of whether “...so that when the lid is positioned above the surface of the multi-well plate and downward force is applied to the lid to press the over against the multi-well plate, the curvilinear concave shaped upper section resiliently deforms to cause the sidewalls to resiliently flex about the multi-well plate and, with continued application of downward force, the sidewalls resiliently grasp the multi-well plate to thereby straighten said upper section to a final, flexed position where the lid is secured to the multi-well plate with the upper section in closely overlying relation to the multi-well plate surface” is a method limitation describing the structural limitation of the sidewalls being formed of resiliently flexible material or a method limitation describing a different structural limitation. If the limitation is describing a structural limitation other than “the sidewalls being formed of the resiliently flexible material”, the structural limitation should be recited in the claims.

5. Regarding claim 16, it is unclear what the location of “...on the sidewall at an end opposite to the end of the sidewall at which the side wall depends from the upper section of the lid” is.

6. Claims 20, 21, 24, 25 are rendered indefinite with “...**sides of the gasket affixed to the sides of the underside of the upper section of the lid** are not in contact with the upper surface of the multi-well plate.” The claim recites that the surfaces of the lid that is physically attached to the underside of the lid do not contact with the upper surface of the multi-well plate. It is unclear whether the claim was intended to recite that intermediate portions of the surface of the gasket facing the upper surface of the multi-well plate contacts the upper surface of the multi-well plate and the peripheral portions of the surface of the gasket facing the upper surface of the

Art Unit: 1743

multi-well plate does not contact the upper surface of the multi-well plate. Claim 21 is rendered indefinite by "...sides of the upper section are urged..." since it does not specify what portions of the upper section is being urged. Claim 25 is rendered indefinite by "...sides of the lid are urged..." since it does not specify what portions of the lid is being urged. Additionally, these claims do not structurally further limit the claims. It is unclear whether additional structure besides the curvilinear of the upper section encourages the phenomena recited in the claims.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

Art Unit: 1743

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 10, 12-14, 16-18, 20-25 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 6,193,064 to Finneran.

Finneran discloses an assembly of a multi-well plate (2) and cover (22) for the multi-well plate (figs. 1-7). The plate comprises an upper surface, plurality of wells (10) with openings disposed in the upper surface, and a skirt disposed on an edge of the plate (figs. 1-7; col. 3, lines 7-17). The cover comprises a lid (22) sized to overlie the multi-well plate and gasket (26) on the underside of the lid (figs. 1-7). The lid comprises an upper section dimensioned to overlie the multi-well plate surface and a plurality of side walls integrally depending from sides of the upper section of the lid and extending substantially perpendicular to the upper section for grasping engagement with the multi-well plate to secure the lid sealingly to the multi-well plate (figs. 2-5, 6B; col. 4, lines 4 and 5). In an initial, unflexed position the upper section of the lid is curvilinear in a concave shape, such that portions of the surface of the gasket facing the upper surface of the multi-well plate intermediate the peripheral portions of the gasket contacts the

Art Unit: 1743

upper surface of the multi-well plate and the peripheral portions of the surface of the gasket facing the upper surface of the multi-well plate are not in contact with the upper surface of the multi-well plate (fig. 6B; col. 4, lines 4 and 5; claims 4, 5, 8). When the lid is positioned above the surface of the multi-well plate and downward force is applied to the lid to press the cover against the multi-well plate, one would expect that the upper section resiliently deform to cause the sidewalls to resiliently flex about the multi-well plate, such that the peripheral portions of the upper section are urged toward the upper surface of the multi-well plate and exert a compressing force on the gasket to compress the gasket between the underside of the lid and upper surface of the multi-well plate to seal the wells in the multi-well plate (fig. 6B). With continued application of downward force, it appears that the sidewalls resiliently grasp the multi-well plate to straighten the upper section to a final, flexed position in which the lid is secured to the multi-well plate with the upper section in closely overlying relation to the multi-well plate surface (figs. 2-5).). Since the upper section and sidewalls of the lid deform in response to the application of force to secure the lid with the multi-well plate by attaching the lugs of the lid to the slots of the multi-well plate, it appears that the lid is formed of a resiliently flexible material. Furthermore, the term flexible is a relative term, and all materials have a certain degree of flexibility, such that the uppersection and sidewalls of the lid of Finneran would have a certain degree of flexibility. The structure and configuration of the lid are the means by which the cover can be aligned with an adjacent cover when the cover is in a stack of like covers (figs. 2-7). The sidewalls include lugs (24) projecting downward from the sidewalls of the lid (figs. 2-7; col. 4, lines 19-23). The lugs fulfill the stacking function in which the cover is stacked directly upon the multi-well plate or indirectly upon the multi-well plate via spacers (figs. 2-7). The lugs also fulfill the clamping

Art Unit: 1743

function in which the cover is clamped to the multi-well plate by their slanted ends, which projects inwardly from the sidewalls (figs. 2-7).

The gasket is dimensioned to compressingly abut the surface of the multi-well plate when the lid is sealingly secured to the multi-well plate and thereby seal the wells against ingress and egress of fluids and materials when the lid is sealingly secured to the multi-well plate (figs. 2-5; col. 4, lines 5-18; claims 5, 6, 11). The gasket is made of a rubber material, such as silicone, natural or butyl rubber, polyisoprene (nature red rubber), polytetrafluoroethylene, or combinations thereof (col. 4, lines 9-18). The gasket has a durometer of Shore 15A or less and having a high degree of chemical resistance to dimethyl sulfoxide since the gasket is made from thermoplastic polymers or elastomers, as disclosed in the instant specification. It appears that the gasket is fixed to the underside of the lid since the gasket remains stationary underneath the lid above the multi-well plate. Furthermore, Finneran discloses that the gasket is within and part of the lid, such that the gasket appears to be affixed to the underside of the cover (col. 4, lines 5-18; claims 5, 6, 11). Regardless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the gasket and cover assembly of Finneran to affix the gasket to the cover for easy and efficient assembling of the apparatus. Additionally, it has been held that forming in one piece an article, which has formerly been formed in two pieces, and put together involves only routine skill in the art (*Howard v. Detroit Stove Works*, 150 U.S. 164 (1893)).

12. Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,193,064 to Finneran in view of U.S. Patent No. 6,486,401 to Warhurst et al.

Art Unit: 1743

Finneran does not disclose the lid with sidewalls including notched tabs with locator holes. Warhurst et al. disclose the lid with sidewalls including notched tabs (29) with locator holes to allow robotic manipulation of the lid by a standard gripper (36) or custom robotic gripper (38) and provide for easy storage (figs. 1-10; col. 2, lines 6-8; col. 4, lines 21-27). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lid of Finneran to include the notched tabs with locator holes of Warhurst et al. to facilitate robotic manipulation of the lid and provide for easy storage.

Finneran does not explicitly disclose the sidewalls of the lid with means for aligning the cover with an adjacent cover when the cover is in a stack of like covers comprising stacking locators, which engage the stacking lugs of the adjacent cover. Warhurst et al. disclose the sidewalls of the lid with means for aligning the cover with an adjacent cover when the cover is in a stack of like covers comprising stacking locators, which engage the stacking lugs that project downward from the sidewalls to allow stacking of assemblies of covered multi-well plates onto one another for efficient storage (figs. 3a, 4; col. 1, lines 12-16; col. 3, lines 38-52). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lid of Finneran to provide the stacking lugs and locators of Warhurst et al. to provide for efficient storage.

13. Alternatively, claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,193,064 to Finneran.

Finneran does not explicitly disclose that the gasket material has a durometer of Shore 15A or less and high degree of chemical resistance to dimethyl sulfoxide. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to

Art Unit: 1743

modify the device of Finneran to make the gasket from a material having a durometer of Shore 15A or less and high chemical resistance to dimethyl sulfoxide in order to obtain a gasket of desired chemical and physical properties as necessary for performing certain assays, for example, a desired degree of flexibility sufficient to seal the wells of a multi-well plate and resistance to dimethyl sulfoxide if dimethyl sulfoxide is used in performing assays.

14. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,193,064 to Finneran in view of U.S. Patent No. 6,379,626 to Munson et al. and U.S. Patent No. 6,103,199 to Bjornson et al.

Finneran does not disclose that the lid is made from steel, spring steel, or stainless steel. However, Munson et al. disclose that the cover is made from stainless steel for corrosion resistance (see COL. 2, lines 59-61). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Finneran to make the cover from stainless steel as in Munson et al. to prevent corrosion.

Finneran do not address the thickness of the cover. However, Bjornson et al. disclose that cover thicknesses are more usually at least about 500 micrometers or 0.019685039370079 inches, which is within the recited range, as required for different materials with different mechanical properties (see COL. 25, lines 65-67; COL. 26, line 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Finneran to provide a cover thickness between 0.015" and 0.024" as in Bjornson et al. to obtain a cover exhibiting certain properties to create an effective seal with the multi-well plate. Furthermore, it has been held that discovering optimum ranges is within ordinary skill in the art (*In re Aller*, 105 USPQ 233).

Art Unit: 1743

15. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,193,064 to Finneran in view of U.S. Patent No. 5,741,463 to Sanadi.

Finneran discloses lugs with slanted edges engage the multi-well plate. Sanadi discloses that a variety of mechanisms, including clips or clamps. In a particular embodiment, Sanadi uses clamps to sealingly secure the lid and gasket onto the plate as an alternative means to clips (see fig. 3). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Finneran to provide clamps on the sidewall at an end opposite to the end of the sidewall that depends from the upper section of the lid to sealingly secure the lid and gasket onto the plate as an alternative means to clips as taught by Sanadi.

Response to Arguments

16. Applicant's arguments with respect to claims 10-25 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 6,518,060 to Heimberg et al. discloses a cover comprising a lid and gasket overlying the multi-well plate. The invention of Heimberg et al. has all structural limitations recited in the instant claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (571) 272-1261. The examiner can normally be reached on M-F (8:00-4:30).


Art Unit: 1743

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elizabeth Quan
Examiner
Art Unit 1743

eq


Jill Warden
Supervisory Patent Examiner
Technology Center 1700